

## Definition of “Producers”

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**Synopsis:** As the Board of Health considers secure medicine return, it must determine which entities are defined as “producers” of “covered drugs” sold in the county. These companies will be responsible for financing and providing the product stewardship program.

Considerations for this decision include:

- Which entities are most appropriate to hold responsible for end-of-life management of the pharmaceutical product.
- Whether entities defined as “producers” can be readily identified and contacted by the Department regarding compliance with the regulation.
- Due to the complexity of the pharmaceutical industry’s manufacturing and distribution network, the definition of “producer” may need to identify multiple entities who could be held responsible, and may need to identify any entities who are not responsible.

### Draft Definition of Producer for Consideration

"Producer" means:

- (a) The person who has legal ownership of the brand, brand name, or cobrand of a covered drug or who manufactures a covered drug sold in or into King County.
- (b) The person who imports a covered drug into King County for sale or distribution if the covered drug is branded or manufactured by a producer that meets the definition under (a) of this subsection and has no physical presence in the United States; or
- (c) If there is no person who is a producer of the covered drug for purposes of (a) or (b), the producer is the person who brings the covered drug into King County for sale or distribution.

Potential exclusions for consideration:

1. Producer does not include pharmacists compounding drugs to be dispensed from the pharmacy in which the drugs are compounded pursuant to prescriptions for individual patients.  
This exemption would be analogous to how WAC code exempts compounding pharmacists from the definition of pharmaceutical manufacturer.
2. Producer does not include a retailer that puts its store label on a covered drug.  
Stewardship policies take different approaches to responsibilities of store brand owners: the B.C. Recycling Regulation captures store brand owners as producers in some circumstances, but the Alameda County ordinance excludes them.

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### Attachments:

- Producer Definition Language from Alameda County Safe Drug Disposal ordinance and WA State Medicine Take-back Bill
- Regulatory Definitions & Terms for Discussion on Defining “Producers” for Product Stewardship Policy